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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,923	07/08/2003	Marie-Claire Grosjean-Courmoyer	A34658-PCT-USA-I (072667.	3094
21003 7590 05/17/2007 BAKER BOTTS L.L.P. 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498			EXAMINER SCHLAPKOHL, WALTER	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 05/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/614,923		GROSJEAN-COURNOYER ET AL.	
	Examiner		Art Unit	
	Walter Schlapkohl		1636	<i>WAL</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 and 30-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-37 and 49 is/are allowed.
- 6) ☒ Claim(s) 20, 38, 39, 43-45 and 48 is/are rejected.
- 7) ☒ Claim(s) 40-42, 46 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/937,236.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the papers filed 2/28/2007 in which claims 21-29 were cancelled, claim 20 was amended, and claims 36-49 were added. Claims 20 and 30-49 are pending and under examination in the instant Office action.

Specification

Applicant's amendment of the title is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

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Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20, 38-39, 43-45 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daboussi (*J. Genet.* 75(3):325-339; of record) in view of Migheli et al (*Genetics* 151:1005-1013, 1999; of record). **This rejection is maintained for reasons of record and extended to new claims 38-39 and 43-45.**

Daboussi teaches a method for identifying a gene associated with a detectable phenotype in a fungus, comprising: (a) transforming the fungus with a polynucleotide comprising a marker gene (*niaD*) which would otherwise be transcriptionally active in the fungus but which has been inactivated by the insertion of an *Impala* transposon, said marker gene comprising, in the direction of transcription, a promoter regulatory sequence of the *niaD* gene under conditions in which transposase is expressed, which allow the excision of the *Impala* transposon from said marker gene and its reinsertion into the genome of the fungus; (b) selecting at least one insertion mutant with said detectable phenotype; and (c) isolating the gene into which or

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close to which the *Impala* transposon has inserted (see entire document, especially pages 334-335, section 7.2 "Development of a gene tagging system" and Figure 4). Although Daboussi does not explicitly teach such a method wherein the *niaD* gene promoter is more than 0.4 kb long, such a limitation is inherent because the reference teaches the use of the (entire) *niaD* gene and not, e.g., the use of a *niaD* gene with a truncated promoter. With regard to new claims 43-44, the *niaD* gene is a reporter gene which is a nitrate reductase. With regard to new claim 48, the transposase in the *Impala* element is controlled by its own promoter.

Daboussi does not teach such a method wherein the *niaD* gene is from *Aspergillus nidulans*.

Migheli et al teach a method for gene tagging comprising the use of a *Fot1* transposon which has been inserted into the *niaD* gene of *Aspergillus nidulans* (see entire document, especially paragraph bridging pages 1007-1008, as well as Figure 1 on page 1008). Migheli et al teach that the use of *niaD* from *A. nidulans* functions as a marker in *nia*⁻ recipient strains (ibid). Migheli et al also teach such a method wherein the transposon used for the tagging carries an *hph*-resistance marker (see, e.g., page 1006, paragraph bridging first and second columns, and page 1012, first paragraph, last sentence).

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Migheli et al teach that this resistance marker could be used in a tagging system which would provide the advantage of a two component system as was previously described for plants (see page 1012, first paragraph, last sentence). Migheli et al also teach that a marker placed in the transposon can be used for testing of transformants for either frameshift, deletion or other disruptions of the transposase associated with the transposon (see paragraph bridging first and second columns on page 1008).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the construct comprising the *niaD* gene of *Aspergillus nidulans* as taught by Migheli in a method of gene tagging wherein the *niaD* gene is interrupted by an *Impala* transposon as taught by Daboussi because both Daboussi and Migheli et al teach methods of gene tagging with the use of *niaD* genes, and Migheli et al teach such a method specifically using the *niaD* gene of *Aspergillus nidulans*. It would also have been obvious for one of ordinary skill in the art to use an *Impala* transposon which carries an additional marker as taught by the combined references because Migheli et al teach that such an additional marker can be used to indicate whether or not the transposase has undergone mutation post-transformation.

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One of ordinary skill in the art would have been motivated to use the *A. nidulans* niaD gene as taught by Migheli et al in the method taught by Daboussi because Migheli et al teach that such a gene from *A. nidulans* is a functional marker within a nia⁻ fungal strain. One of ordinary skill in the art would have been motivated to place an additional marker within the transposon not only for the added benefit of testing whether the transposase had undergone frameshift, deletion or disruption as taught by Migheli et al, but also because such a marker, in the context of a gene tagging system, would provide the basis of a two-component system as had already been described in plants.

Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result when combining the method of gene identification comprising the use of a niaD gene as taught by Daboussi with the teachings of Migheli et al.

Response to Arguments

Applicant argues that either as a result of amendment or cancellation, the rejection of the claims under 35 USC 103 is moot. Applicant further argues that the rejection should not be applied to the new claims which focus on the inventive method as

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applied to *Magnaporthe grisea* (claims 36-37), require that a transposase be provided (new claims 38-48), or relate to a promoter trap (new claim 49). Applicant further argues that the cited references do not address how to solve the problem of absent or inefficient transposition of *Impala* as occurs in *M. grisea*. Applicant further argues that this obstacle is overcome by the present invention by the provision of two complementary approaches: "using a double selection process to collect cells in which transposition has occurred (the first selection) and that exhibit the phenotype of interest (the second selection) and/or providing a transposase able to mobilize the *Impala* element" (see page 10, last paragraph or the Remarks filed 2/28/2007). Finally, Applicant argues, because neither Daboussi nor Migheli or their combination would lead the skilled artisan to arrive at these aspects of the presently claimed invention with any reasonable expectation of success, they should not be considered to render the claims obvious.

Applicant's arguments have been carefully considered and have respectfully been found unpersuasive. To begin, Applicant's amendment does not further limit claim 20 to embodiments wherein the marker gene is selected from the group consisting of glucouronidase, GFP, hygromycin, phleomycin, sulfonyl urea, and the gene that confers tolerance to the

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herbicide bialaphos. Therefore, Applicant has not incorporated ALL the limitations of prior claims 22-24 into claim 20 and the claim still comprises an embodiment which is rejected under 35 U.S.C. 103 over Daboussi in view of Migheli, i.e., the transformation of a fungus with a polynucleotide comprising a marker gene which would otherwise be transcriptionally active in the fungus but which has been inactivated by the insertion of an *Impala* transposon, said marker gene comprising in the direction of transcription, a promoter regulatory sequence of the *niaD* gene from *A. nidulans* which is more than 0.4 kb long and which is functionally linked to the coding sequence of said marker gene under conditions in which transposase is expressed and which allow the excision of the *Impala* transposon from said marker gene and its reinsertion into the genome of the fungus. Furthermore, this rejection is appropriately extended to new claims 38-39 because 1) the combination of the references anticipates the claim limitation that a transposase be provided because the *Impala* transposon provides the transposase, and 2) the *niaD* gene from *A. nidulans* is functional in *M. grisea*. Thus, Applicant's argument that the present invention solves the problem left unaddressed by the prior art by the use of a double selection process to collect cells in which transposition has occurred (the first selection) and that exhibit the phenotype of

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interest (the second selection) and/or providing a transposase able to mobilize the *Impala* element is not persuasive because 1) Daboussi utilizes a double selection protocol, i.e., both *niaD* status and a change in phenotype are clearly utilized to identify tagged genes, and 2) a transposase is provided in the *Impala* transposon taught by Daboussi.

Allowable Subject Matter

Claims 30-36 and 39 are allowed.

Claims 40-42 and 46-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

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expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify

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applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.


For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Joseph Woitach can be reached at (571) 272-0739.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

May 8, 2007


DAVID GUZO
PRIMARY EXAMINER